DEPARTMENT OF STATE REVENUE

Revenue Ruling #2014-04ST
May 1, 2015

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ISSUES

Sales and Use Tax - Exemptions Applicable to Sales of Medical Supplies and Devices

Authority: IC 6-2.5-1-18; IC 6-2.5-1-25; IC 6-2.5-2-1; IC 6-2.5-3-2; IC 6-2.5-5-18; 45 IAC 2.2-5-27; 45 IAC 2.2-5-36; Sales Tax Information Bulletin #48 (August 2008)

A company ("Taxpayer") is seeking a determination regarding whether its product is exempt from gross retail and use tax.

STATEMENT OF FACTS

Taxpayer is in the business of developing and commercializing a method of treating solid tumors by means of "low intensity[,] alternating electric fields to exert physical forces on the electrically charged components of dividing cancer cells, which is intended to disrupt cell division and cause cancer cell death" (the "Treatment"). Taxpayer describes the Treatment as follows in pertinent part:

> [The treatment] is delivered via a treatment which allows patients to maintain their normal daily activities while receiving continuous anti-cancer treatment. [Taxpayer] developed [Treatment] to treat solid tumors of the head. The treatment works by producing alternating electrical fields within the human body that are believed to disrupt the rapid cell division exhibited by cancer cells. The alternating electrical fields are applied to the brain through electrodes placed on the scalp.
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> In April 2011, [Taxpayer] received FDA approval to market the [Treatment] as a stand-alone treatment for adults with confirmed gliobastoma or GBM that recurs (referred to as recurrent GBM). GBM is the most common and most aggressive malignant brain tumor. The approval is based on a Phase 3 study which demonstrated that [the Treatment] was equally as effective as standard of care chemotherapy for the treatment of recurrent GBM. Patients with recurrent GBM face a poor prognosis with a one-year survival rate of approximately 10% and a median overall survival time of three to five months when left untreated.
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> The FDA issues approvals for new drugs, biological licenses and pre-market approval ("PMA") devices. Medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval. The [Treatment] is a PMA approved device.
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> The PMA pathway is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of [C]lass III devices. Therefore, these devices require a [PMA] application under section 515 of the FD&C Act in order to obtain marketing clearance.
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> PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). An approved PMA is, in effect, a government issued license granting the applicant (or owner) permission to market the device in the United States. The PMA owner, however, can authorize the use of its data by another.

Conversely, durable medical equipment is generally marketed under a different registration pathway as they are generally Class I or II medical devices.

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There are 3 primary components to the [Treatment]:

- An electric field generator, connection cables, a portable battery, power supply, rack and a power cord.
- INE transducer arrays.
- Ancillary items and accessories consisting of boxes, . . . bags, operations manuals and self-exchange kits.

The [Treatment] is designed for continuous use throughout the day - the patient is able to maintain a normal daily routine while treating the disease.

- The [Treatment] delivers non-invasive alternating electric fields through insulated array's that are attached to the mechanism and placed directly on the skin in the region surrounding the tumor. Typically the arrays are removed and replaced two to three times per week. The arrays are replaced to ensure sufficient contact with the patient's skin.
- The components of the [Treatment] are small, weighing six pounds, and are powered by a rechargeable battery in a bag that is carried by the patient so they can maintain mobility.
- The system can be plugged in while the patent is stationary.
- Patients pay a monthly fee for the [Treatment] which is broken down into a charge for the durable components and a monthly fee to purchase transducer arrays.
- Around the clock technical support is included in the fees.

. . .

To obtain the [Treatment], certified physicians write a prescription for the patient and submit the prescription to [Taxpayer's] shipping facility location. . . The prescription is filled and the components of the [Treatment] are shipped to the closest local technical support staff specialist or to the certified physician's office. The patient will receive an agreement to review and sign once they are trained how to apply the [Treatment] themselves. The technical staff and the certified physician are trained on how to administer the [Treatment] to the patient in advance.

The day the patient starts treatment, the local technical staff delivers the components of the therapy to the patient, they train and educate the patient on the proper way to administer the treatment and the technical aspects of the [Treatment]. The patient is provided with a user manual and technical support phone number. The patient then receives additional training and guidance and treatment initiation from their physician. The ongoing care of the patient and the medical assessments are conducted by the treating physician. All medical questions are referred to the treating physician.

It is the patients' responsibility to request additional arrays. [Taxpayer] replaces batteries once capacity falls below a certain threshold. After initial treatment starts [Taxpayer] typically ships arrays and other components directly to patients.

[Taxpayer] bills the patients' 3rd party insurance provider, managed care company or in some cases, the patient directly. If a patient decides to discontinue the therapy they return the equipment and any remaining supplies to [Taxpayer] at [Taxpayer's] expense. As the arrays cannot be reused, [Taxpayer] is responsible for collection and proper disposition of the arrays.

[Taxpayer] provides a monthly invoice that includes all equipment and transducer arrays in one consolidated charge.

DISCUSSION

Taxpayer requests that the Department rule whether the Treatment is exempt from gross retail and use tax as either a prosthetic device or durable medical equipment.

Indiana imposes an excise tax called "the state gross retail tax" (or "sales tax") on retail transactions made in Indiana. IC 6-2.5-2-1(a). A person who acquires property in a retail transaction (a "retail purchaser") is liable for

the sales tax on the transaction. IC 6-2.5-2-1(b). Indiana also imposes a complementary excise tax called "the use tax" on "the storage, use, or consumption of tangible personal property in Indiana if the property was acquired in a retail transaction, regardless of the location of that transaction or of the retail merchant making that transaction." IC 6-2.5-3-2(a).

In general, all purchases of tangible personal property are subject to sales and/or use tax unless an enumerated exemption from sales and/or use tax is available. IC 6-2.5-5-18(a) provides the following:

> Sales or rentals of durable medical equipment, mobility enhancing equipment, prosthetic devices, artificial limbs, orthopedic devices, dental prosthetic devices, eyeglasses, contact lenses, and other medical supplies and devices are exempt from the state gross retail tax, if the sales or rentals are prescribed by a person licensed to issue the prescription.

In order to be exempt as durable medical equipment, prosthetic devices, artificial limbs, orthopedic devices or other medical supplies and devices, the item(s) at issue must be sold or rented to a purchaser pursuant to a valid prescription. Implicit in that requirement is the necessity that the item be transferred for consideration to a purchaser who possesses a prescription for the item. 45 IAC 2.2-5-27 clarifies the definition of "prescribed" as follows:

> (a) The term "person licensed to issue a prescription" shall include only those persons licensed or registered to fit and/or dispense such devices.
> (b) Definition: The term "prescribed" shall mean the issuance by a person described in [subsection (a)] of a certification in writing that the use of the medical equipment[,] supplies[,] and devices is necessary to the purchaser in order to correct or to alleviate a condition brought about by injury to, malfunction of, or removal of a portion of the purchaser's body.

When sold to a physician or hospital, the device is not sold to a purchaser who possesses a prescription for the item and, therefore, such a transaction is not exempt from Indiana sales and use tax pursuant to IC 6-2.5-5-18.

Taxpayer's position is that the Treatment is either a prosthetic device or durable medical equipment.

A. Prosthetic Device

Taxpayer primarily asserts that its Treatment is a prosthetic device. The term "prosthetic device" is defined in IC 6-2.5-1-25 as:

> [A] replacement, corrective, or supportive device, including repair and replacement parts for the device, worn on or in the body to:
> (1) artificially replace a missing part of the body;
> (2) prevent or correct physical deformity or malfunction; or
> (3) support a weak or deformed part of the body.

Taxpayer maintains that the Treatment "serves to assist and correct the human immune system, which is malfunctioning by not being capable of destroying the cancer cells." Taxpayer also makes the argument that the Treatment acts "as a substitute for the human immune system."

Taxpayer further notes that the Ohio Department of Taxation recently issued an advisory letter that determined that the Treatment was exempt as a prosthetic device. Ohio, like Indiana, is a member of the Streamlined Sales Tax Project ("SSTP"), and their definition of "prosthetic device" is nearly identical to Indiana's definition. Taxpayer makes the argument that one of the SSTP's purposes is for "definitions . . . to be applied in the same manner from state to state."

Analyzing the Treatment in the context of the plain meaning in IC 6-2.5-1-25, the Treatment could arguably be considered a "corrective device" which "corrects a physical malfunction;" however, Taxpayer acknowledges later in its request that the Treatment is not worn on the body, and to be considered a prosthetic device, the device must be "worn on or in the body." The Treatment is instead attached to a patient's head. The Ohio advisory letter determined that the Treatment was a prosthetic device and not durable medical equipment because it was worn on the body, but the Department cannot reach the same conclusion since the Treatment is not worn on or in the body. Therefore, the Treatment is not a prosthetic device.

B. Durable medical equipment

Taxpayer also makes the case that the Treatment is "durable medical equipment" if it is determined not to be a prosthetic device. "Durable medical equipment" is defined in IC 6-2.5-1-18, which provides:

> (a) "Durable medical equipment" means equipment, including repair and replacement parts for the equipment, that:
> (1) can withstand repeated use;
> (2) is primarily and customarily used to serve a medical purpose;
> (3) generally is not useful to a person in the absence of illness or injury; and
> (4) is not worn in or on the body.
> The term does not include mobility enhancing equipment.
> (b) As used in this section, "repair and replacement parts" includes all components or attachments used in conjunction with durable medical equipment.

The Department's Sales Tax Information Bulletin #48 ("STIB 48") further clarifies the exemption for durable medical equipment as it applies to purchases made by patients pursuant to a prescription by a licensed practitioner:

> • Sales of durable medical equipment that can stand repeated use; is primarily used to serve a medical purpose; is generally not useful to a person in the absence of an illness or injury; is not worn in or on the body; and is directly required to correct or alleviate injury to, malfunction of, or removal of a portion of the human body; and
> • Sales of repair and replacement parts for the previously mentioned durable medical equipment.

Taxpayer maintains that the Treatment "can withstand repeated use (i.e., it is not disposable), solely serves a medical purpose and is only useful in the treatment of cancer, is not worn on the body, and is only available through a prescription." The Treatment can be carried, but Taxpayer assures the Department that it "is carried in the same manner as many other devices considered durable medical equipment." Taxpayer compares the Treatment to dialysis machines, which, as Taxpayer points out, the Department lists in its "Taxability Matrix" as exempt from sales tax if it is purchased by a patient with a prescription.[1] A home dialysis machine consists of a main unit and tubing connecting the main unit to the patient. Likewise, the Treatment consists of a main unit and two sets of electrodes connected to the patient.

Taxpayer further emphasizes that chemotherapy and other drugs used to treat GBM and similar conditions when sold and rented as prescribed to a patient by a licensed physician are exempt from sales tax. If the Department does not find that the Treatment is exempt from sales tax, then it would result in an "odd" outcome.

Taxpayer has established that the Treatment is prescribed to patients, as it is "necessary to the purchaser in order to correct or to alleviate a condition brought about by injury to, malfunction of, or removal of a portion of the purchaser's body." 45 IAC 2.2-5-27. Taxpayer has also sufficiently established that the Treatment falls within the definition of "durable medical equipment." The Treatment can stand repeated use, since it is not meant to be used only once; it is primarily used to serve a medical purpose, and it appears to be only used to serve a medical purpose; it would not be useful to a person in the absence of an illness or injury; it is not worn in or on the body, although it is attached to the body; and it is directly required to correct or alleviate injury to, malfunction of, or removal of a portion of the human body. As such, the Treatment falls within the exemption set out in IC 6-2.5-5-18(a).

Further, in addition to the Treatment being prescribed to patients, Taxpayer has established that the Treatment is sold to patients, that patients pay for it themselves or through their insurance, and that the Treatment is delivered to the patients. The patients also use the Treatment themselves, at their home or at work, and without the aid of the prescribing physician (except that their prescribing physician is trained on how to use the Treatment and may presumably administer it at times). In other words, it is not a type of medical supply purchased by a licensed practitioner and consumed in their professional use. 45 IAC 2.2-5-36.

Finally, there remains an issue as to whether the replacement arrays and batteries are considered exempt. Taxpayer points out that "'repair and replacement parts' includes all components or attachments used in conjunction with durable medical equipment." The Department concurs that the replacement arrays and batteries would be exempt from sales tax.

RULING

The Treatment is considered durable medical equipment, and as such the Treatment and its repair and replacement parts are exempt from sales tax if sold or rented to a patient by a licensed practitioner pursuant to a prescription.

CAVEAT

This ruling is issued to the taxpayer requesting it on the assumption that the taxpayer's facts and circumstances as stated herein are correct. If the facts and circumstances given are not correct, or if they change, then the taxpayer requesting this ruling may not rely on it. However, other taxpayers with substantially identical factual situations may rely on this ruling for informational purposes in preparing returns and making tax decisions. If a taxpayer relies on this ruling and the Department discovers, upon examination, that the fact situation of the taxpayer is different in any material respect from the facts and circumstances given in this ruling, then the ruling will not afford the taxpayer any protection. It should be noted that subsequent to the publication of this ruling a change in statute, regulation, or case law could void the ruling. If this occurs, the ruling will not afford the taxpayer any protection.

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[1] http://www.streamlinedsalestax.org/uploads/downloads/State%20Compliance/Indiana/2013/Indiana%20Taxability%20Matrix%202013.pdf

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